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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,193	01/03/2006	Masaaki Miyazawa	63283(50221)	6284

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,193	MIYAZAWA ET AL.	
	Examiner	Art Unit	
	LOUISE HUMPHREY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-14,16,17,22,26,29,31,35,38-40,44,45,47,48,50-54,57-59,61-65,67,68 and 70.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,15,18-21,23-25,27,28,30,32-34,36,37,41-43,46,49,55,56,60,66 and 69.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,3-14,16,17,22,26,29,31,35,38-40,44,45,47,48,50-54,57-59,61-65,67,68 and 70.

DETAILED ACTION

This Office Action is in response to the preliminary amendment filed on 13 April 2005. Claims 2, 15, 18-21, 23-25, 27, 28, 30, 32-34, 36, 37, 41-43, 46, 49, 55, 56, 60, 66 and 69 have been cancelled.

Claims 1, 3-14, 16, 17, 22, 26, 29, 31, 35, 38-40, 44, 45, 47, 48, 50-54, 57-59, 61-65, 67, 68 and 70 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. §121 and §372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 3-13, drawn to the special technical feature of a method of determining a predisposition to infection comprising assaying DNA samples for alleles at microsatellite loci.

Group II, claim 14, 16 and 61-65, drawn to the special technical feature of a nucleic acid encoding a locus controlling production of neutralizing antibodies to HIV; a vector comprising at least one microsatellite loci or complement, fragment, variant or homolog thereof; and a kit for a diagnosis of infection comprising reagents for genotyping at lease one microsatellite loci.

Group III, claims 17 and 67, drawn to the special technical feature of a method of treating a subject comprising administering a gene therapy comprising a vector comprising at least one microsatellite loci or complement, fragment, variant or homolog thereof, or administering a medicament produced from the nucleic acid encoding a locus controlling production of neutralizing antibodies to HIV

Group IV, claims 22, 26, 29 and 31, drawn to the special technical feature of a peptide or its derivatives, homologs, or fragments thereof comprising an amino acid sequence

encoded by a gene located in a chromosomal segment adjacent to microsatellite loci or its complement or homolog; a pharmaceutical composition comprising the peptide; a contraceptive comprising the peptide; and a microbicide comprising the peptide.

Group V, claims 35 and 67, drawn to the special technical feature of a method for treatment or prophylaxis of infection comprising administering a peptide or its derivatives, homologs, or fragments thereof comprising an amino acid sequence encoded by a gene located in a chromosomal segment adjacent to microsatellite loci or its complement or homolog.

Group VI, claims 38-40, drawn to the special technical feature of a vaccine comprising a DNA sequence comprising a microsatellite loci or fragments, variants, complements, or homologs thereof.

Group VII, claim 44, drawn to the special technical feature of a chip or assay plate comprising DNA of a microsatellite loci or its fragments, variants, complements, or homologs thereof.

Group VIII, claim 45, drawn to the special technical feature of a method of screening for a compound that binds the DNA of a microsatellite loci or its fragments, variants, complements, or homologs thereof, on a chip or assay plate.

Group IX, claim 47, drawn to the special technical feature of a chip or assay plate comprising a peptide or its derivatives, homologs, or fragments thereof comprising an amino acid sequence encoded by a gene located in a chromosomal segment adjacent to microsatellite loci or its complement or homolog.

Group X, claim 48, drawn to the special technical feature of a method of screening for a compound that binds, on a chip or assay plate, a peptide or its derivatives, homologs, or fragments thereof comprising an amino acid sequence encoded by a gene located in a chromosomal segment adjacent to microsatellite loci or its complement, variant or homolog thereof.

Group XI, claims 50 and 51, drawn to the special technical feature of a method of producing an immunoglobulin A comprising contacting a cell with a microsatellite loci, or its complement, variant or homolog thereof.

Group XII, claims 52, 53 and 58, drawn to the special technical feature of an immunoglobulin A; a pharmaceutical composition comprising an immunoglobulin A; and a mucosal vaccine comprising the immunoglobulin A.

Group XIII, claims 54, 57 and 59, drawn to the special technical feature of a method comprising administering to a subject an immunoglobulin A.

Group XIV, claims 70, drawn to the special technical feature of a method for the treatment or prophylaxis of HIV infection comprising administering a peptide encoded by a locus controlling neutralization of antibodies to HIV.

Group XV, claim 68, drawn to the special technical feature of a peptide encoded by a locus controlling neutralization of antibodies to HIV.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each group requires a technical feature that is not required by any of the other groups.

The first common technical feature among these inventions is the method for screening DNA in a sample for susceptibility to an infection using microsatellite markers. Such a method is disclosed in Norose *et al.* (April 2002). Therefore, the technical feature is not a contribution over the art, thus, the claimed invention cannot be said to have unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The microsatellite loci species are as follows:

D22S929, D22S277, D22S264, D22S423, D22S418 and D22S272.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All species are present in all the pending claims.

The following claim(s) are generic: 1, 3, 13, 14, 16, 39, 44, 45, 48, 50, 51, 64 and 65.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the same reasons as set forth above for the Groups of inventions.

Restriction to Single Sequence Election

Note that this is not a species election and is separate from a group election.

Claim 38 specifically recites multiple sequences encoding different proteins, which are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. §121. Each such nucleic acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR 1.141 *et seq* (See MPEP §803.04). Each sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being

essential to that utility. As such, sequences in each of claims 6-9 and 11 are not considered to constitute a proper genus/Markush, and are therefore subject to additional restriction.

Furthermore, a search of more than one (1) of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. Each of the SEQ ID NO's is a unique and separately patentable sequence, requiring a non-coextensive search for the prior art.

In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants must further elect ONE sequence, identified by a single SEQ ID NO., which if determined to be patentable, would also be patentably distinct from other sequences. Failure to elect a specific sequence will be considered to be non-responsive reply.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LOUISE HUMPHREY whose telephone number is (571)272-5543. The examiner can normally be reached on Mon-Thu, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 1648
27 February 2009
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648